European Food Safety Authority

EXECUTIVE DIRECTOR

Parma, 28/04/2010
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Ms Paola Testori Coggi
Director General of DG Health and Consumers
European Commission
Rue Breydel, 4
B-1049 Brussels

Re: Post market environmental monitoring of genetically modified organisms

Dear Ms Testori Coggi, Dear Paola,

I am writing to you with reference to the visit of Commissioner Dalli to EFSA's premises on 12 March 2010. During his stay at EFSA Commissioner Dalli stressed the importance post market environmental monitoring of genetically modified organisms should play following their authorisation in the European Union. With this letter, I would like to reiterate EFSA's commitment and willingness to provide the most appropriate scientific and technical assistance to the competent services of the Commission in this matter to keep improving EFSA's contribution to the Post Marketing Environmental Monitoring (PMEM) process.

As you are aware, in 2006, the GMO Panel published an opinion on PMEM. In that opinion, the GMO Panel presented guidance for applicants for developing PMEM plans. In addition, under the legal framework provided by Directive 2001/18/EC and Regulation (EC) No 1829/2003, EFSA is required in its scientific opinion on each application submitted under those legal acts, to specify, where appropriate, any conditions or restrictions that should be imposed on the placing on the market of the relevant GMO and any specific conditions or restrictions for its use and handling, including PMEM requirements. In the case of GMOs or food or feed containing or consisting of GMOs, EFSA also specifies, where appropriate, the conditions for the protection of particular ecosystems/environment and/or geographical areas. Implementation of PMEM plans are under the responsibility of the Member States.

According to the legal framework and EFSA guidance document for renewal applications, the reports on PMEM are part of the renewal applications. It is therefore very important for EFSA that the data collected during the PMEM contribute to a sound basis for scientific assessment of renewal applications. Consequently, the PMEM plan submitted for each application should adequately take into consideration harmonization and coordination of data collection. Against this background, EFSA is willing to review its 2006 scientific opinion on PMEM guidance, in order to specify further the requirements for a coherent and comprehensive PMEM plan to be submitted for each application.

Further, EFSA is ready and committed to provide scientific support, should the European Commission request from EFSA, in cooperation with the National Competent Authorities, to conduct a regular assessment of the data resulting from the PMEM of each authorised GMO. When the PMEM plan for a specific authorisation has been developed by the relevant Member States, EFSA would also of course be ready to assist the European Commission through a consultation on the scientific rationale and content of the plan.

I would welcome the opportunity to further discuss this with you and your services.

Yours sincerely,

Catherine Geslain-Lanéelle

Cc: Ms. Joanna Darmanin; Mr Harald Kandolf (Cabinet of Commissioner Dalli).
Mr Bernard Van Goethem (DG SANCO).